



NHS Trust

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19 May 2017

updated 30 May 2017, 6 July 2017, 30 August 2017

Suppliers of G6PD assay reagents

Dear colleagues,

Many participants have been notified by Trinity Biotech that production of the 345 assay kit for the quantitation of G6PD activity has been suspended until the end of 2017. At the time of this notice, I can see no further information on the Trinity Biotech website although contact details are provided in the notification from Trinity Biotech. The table below shows details of the different providers' kits and reagent systems registered by participants in the UK NEQAS Haematology G6PD quantitative assay scheme.

Method	Web address
Trinity Biotech 345	http://www.trinitybiotech.com/area/g-6-pdh/
Sentinel Diagnostics	http://www.sentinel.it/en/
Randox Reagent	http://www.randoxonlinestore.com/Reagents/G-6-pdh-assay-p-8165
Pointe Scientific	http://www.pointescientific.com/diagnostic_reagents/product/44
BCS Biotech	None available - ? no longer trading
Instruchemie	http://instruchemie.nl/
In-house reagent	None available – UK NEQAS may be able to facilitate exchange of information between sites
"Other" or no method registered	None available – these participants have not provided method details other than assay temperature.

Information from the websites of these alternative suppliers is attached to this document with a copy of the notice from Trinity Biotech. Some details of other manufacturers of kits that are not registered by participants in the UK NEQAS scheme are also attached in this document with details from their websites.

Inclusion of any manufacturer in this document does not imply endorsement of the product by UK NEQAS and none of the kits have been validated by us for use.

If you would like further assistance or can offer additional information that may be of use to other participants, please contact me directly (<u>barbara.delasalle@whht.nhs.uk.</u>

With best regards,

DeloSalla

Barbara De la Salle Director, UK NEQAS Haematology

CDH336v5 Field Notice G6_20170519 Issued 30-8-17





17th May 2017 Bray, Ireland

Notification re: Suspension of G6PDH 345A & 345B Kits

Dear Valued Customer,

Trinity Biotech regrets to inform you that we will temporarily suspend, with immediate effect, the manufacture of the following products:

- Code 345A, Glucose-6-Phosphate Dehydrogenase (G-6-PDH)
- Code 345B, Glucose-6-Phosphate Dehydrogenase (G-6-PDH)

Trinity Biotech took the decision to suspend these products due to our inability to consistently manufacture. Trinity Biotech will continue to support all products currently in use until such time as they expire.

The company has already initiated a project to reinstate these products in 2018. All customers will receive an update on progress in November 2017.

Trinity Biotech sincerely apologises for the inconvenience due to the suspension. If you have any questions regarding this notification, please don't hesitate to contact us at <u>micheal.roche@trinitybiotech.com</u> or <u>claire.collins@trinitybiotech.com</u>

Yours sincerely,

Micheál Roche Vice President of Sales and Marketing ID/POC/CC

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Trinity Biotech Manufacturing Limited Registered in Ireland, Registration number 239206 Directors: Dr. J Walsh, Kevin Tansley.



http://www.sentinel.it/en/

Follow the links on the page under 'Laboratory' to Clinical Chemistry and then Reagents

Glucose-6-phosphate dehydrogenase

G6P-DH 124 mL (1x100+1x2+1x2+1x20)

Enzymatic UV method with NADP on erythrocytes - Wavelength 340 nm - THREE REAGENTS, stable at least 4 weeks after preparation - Kinetic reading - Lag phase 0 sec - Reading 3 min - Total reaction time 8 min (erythrocytes). Recommended controls: (REF G5888 Control Deficit, REF G5029 Control Intermediate and REF G6888 Control Normal) – Available through Trinity Biotech - Ireland.

17005

100 mL

Colorimetric

RANDOX

http://www.randoxonlinestore.com/Reagents/G-6-pdh-assay-p-8165

G-6-pdh assay

Product	Method	Size	Catalog	Price	Quantity
G-6-pdh assay	UV	R1 1 x 100ml, R2 1 x 2ml	PD410	\$156.01	1
Add to Cart <u>Save for Later</u>					

Shipping costs will be added at the checkout stage, click here for charges.

•	Format			
	Lyophilized			
•	Assay			Range
	154 - 4303U/L			
•	Working	Stability	15-25	°C
	_			
•	Working	Stability	2-8	°C
	28 days			
	Request Kit Insert			

Intended Use

For the quantitative in vitro determination of Glucose-6-Phosphate Dehydrogenize in erythrocytes. This product is suitable for both manual and automated use.

Clinical Significance

The enzyme Glucose-6-Phosphate Dehydrogenize (G6PDH) plays a major role in protecting the red blood cells from oxidative damage which can alter the structure causing them to lyse.

G6PDH deficiency is one of the most common enzyme deficiencies in the world, it is a genetic disorder resulting from one or more mutations in the gene coding for G6PDH. Mutation can affect the stability or functionality of the enzyme and ultimately leads to decreased enzyme activity.

Hemolytic anemia is perhaps the most common problem resulting from G6PDH deficiency and occurs when the red blood cells are destroyed at an accelerated rate before the body can replace them. G6PDH deficiency may also be associated with jaundice.

Principle

The enzyme activity is determined by measurement of the rate of absorbance change at 340 nm due to the reduction of NADP+.

Available Applications

Various



http://www.pointescientific.com/ Listed under Products G6PD CATALOG #: G7583

METHOD Glucose-6-Phosphate, Kinetic

TECHNICAL INFORMATION Format: Dry Powder Wavelength: 340 nm Linearity: 21.0 U/g Hb Expected Values: 12.1±2.09 U/g Hb Storage Temperature: 2-8°C Reconstituted Stability: 8 hrs at RT, 5 days at 2-8°C



DESCRIPTION

- ORDERING INFORMATION
- RELATED PRODUCTS
- DOCUMENTATION
 Intended Use

For the quantitative, kinetic determination of glucose-6-phosphate dehydrogenase (G6PD) in blood at 340nm. For in vitro diagnostic use only.

Principle

Glucose-6-phosphate dehydrogenase (G6PD, D-glucose-6-phosphate: oxidoreductase, EC 1.1.1.49) catalyzes the first step in the pentose phosphate shunt, oxidizing glucose-6-phosphate (G-6-P) to 6-phosphogluconate (6-PG) and reducing NADP to NADPH. This procedure is a modification of the spectrophotometric methods of Kornberg and Horecker and of Lohr and Waller, involving the following reaction: Nictotinamide adenine dinucleotide phosphate (NADP) is reduced by G6PD in the presence of G-6-P. The rate of formation of NADPH is proportional to the G6PD activity and is measured spectrophotometrically as in increase in absorbance at 340nm. Production of a second molar equivalent of NADPH by erythrocyte 6-phosphogluconate dehydrogenase (6-PGDH) is prevented by use of maleimide, an inhibitor of 6-PGDH.

Pointe Scientific kits are supplied in the UK through:





http://www.biosentec.fr/en/

Products > Medical Biology >

HEMATOLOGY

Assay Of Enzymatic Activities

REF.	PRODUCT	SPECIFICATION	PRICE	DOCUMENTATION	ORDER
ASSAY	OF ENZYMATIC ACTIVITIES				
063	Pyruvate kinase	20 tests. Enzymatic reaction.	0,∞€	Product Info 🔁	ځ
064	Glucose 6- Phosphate Dehydrogenase	20 tests. Enzymatic reaction.	0,∞€	Product Info 🔁	
					<u>Order</u>

Тор

G6PDH - GLUCOSE 6 PHOSPHATE DEHYDROGENASE

Reference Size Product G6P8906 285 T- 4x15mL G6P8905T 285 T- 20x3mL G6PDH - GLUCOSE 6 PHOSPHATE DEHYDROGENASE G6P8905 285 T- 20x3mL G6PDH QUANTITATIVE KINETIC UV assay on WHOLE BLOOD. G6P8906 285 T- 4x15mL G6P8905T 285 T- 20x3mL G6PDH - GLUCOSE 6 PHOSPHATE DEHYDROGENASE G6P8905 285 T- 20x3mL G6PDH QUANTITATIVE KINETIC UV assay on WHOLE BLOOD. G6CAL3 2 x 0.5 mL **G6PDH CALIBRATORS** Lyophilized calibrators for QUANTITATIVE UV determination of Glucose-6-Phosphate **Dehydrogenase(G6PDH) and COLORIMETRIC of TOTAL HEMOGLOBIN on ERYTHROCYTES.** G6CON 3 x 0.5 mL **G6PDH CONTROLS SET**

Lyophilized controls for QUANTITATIVE UV determination of Glucose-6-Phosphate Dehydrogenase (G6PDH) and COLORIMETRIC of TOTAL HEMOGLOBIN on ERYTHROCYTES.

https://www.bensrl.it



www.rddiagnostics.com

G-6-PD quantitative kit(s)

Available in a box for 300 tests (**Cat.No OSMMR300**) or 2000 tests (**Cat.No OSMMR2000**). Our 2.000 test kit is available in two formats to suit the needs of big and small screening centers. Thus, there is a 20 vials X 100 test format (**Cat.No OSMMR2000/100**) and a 4 vials X 500 test format (**Cat.No OSMMR2000/500**). Each vial is stable for 5 days after reconstitution refrigerated. Therefore, our product range covers the needs of labs performing 20 - 2000 tests per day. It is a fully quantitative test, very easily automated. Results obtained in U/g Hb. Measured at 340nm in kinetic mode.

Available as a box containing 10 single test vials (**Cat.No MMR010**). Suitable for small or private labs. Can be worked on all automated analyzers or manually. No chemicals lost ! A very easy, two step protocol will give you results in less than 15 minutes. It can be also used with a microplate reader or a simple spectrophotometer. Measured at 340nm in kinetic mode.

Available as a diaphorase - color reagent kit, in a box of 100 (1 X 100 test vial; **Cat.No OSMMR-D100**) or 1000 tests (10X100 test vials ; **Cat.No OSMMR-D1000**). Each vial is stable for 5 days after reconstitution refrigerated. Measured at 550nm in kinetic mode.

G-6-PD qualitative kit (UV lamp method)

Available in a box of 500 (**SQMMR500**, 10 vials X 50 tests) or 1250 tests (**SQMMR1250**, 5 vials X 250 tests). Visual estimation of G-6-PD activity under special UV lamps.





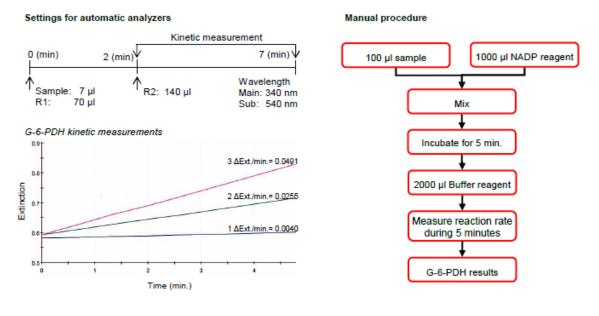
G-6-PDH

G-6-PDH

DETERMINATION OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE (EC 1.1.1.49) IN ERYTHROCYTES HAEMOLYSATE

Enzymatic method Suitable for all analyzers – 300 tests Product insert with instructions for automated and manual procedures Stability reagents > 8 years after production PK / G-6-PDH controls available





Linearity: 4500 U/I Mean CV's: 2.28% Mean recovery: 99.6% Correlation compared to other manufacturers: 0.991

roduct name	Product no.	Quantity	
-PDH Reagent Set	2958	25 -300 tests	
G-6-PDH Calibrator	2971	1 x 500 µl	MULTICEV AF
G-8-PDH Control Deficient Level	3141	1 x 500 µl	I man in the Co
G-6-PDH Control Normal Level	3142	1 x 500 µl	
G-6-PDH Control High Level	3143	1 x 500 µl	
G-6-PDH Digitonin Hemolyzing Reagent	3028	1 x 60 ml	